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APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/086,059	02/27/2002	Jose Gutierrez-Rocca	540591-7095.1	1436	
20999 7	7590 06/30/2003				
	LAWRENCE & HAUG	EXAMINER			
745 FIFTH AV NEW YORK, I	VENUE- 10TH FL. NY 10151	CRIARES, THEODORE J			
			ART UNIT	PAPER NUMBER	
			1617	5	
		DATE MAILED: 06/30/2003			

Please find below and/or attached an Office communication concerning this application or proceeding.

	•		Application No	р.	Applicant(s)					
			10/086,059	<u>-</u>	GUTIERREZ-ROCCA ET AL.					
	Office	Office Action Summary		ner Art Unit						
			Theodore J. C		1617					
	The MAILI Period for Reply	The MAILING DATE of this communication appears on the cover she t with the correspondence address Period for Reply								
	A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status									
	1)⊠ Responsiv	e to communication(s) filed on 27 F	ebruary 2002 .		•					
	2a)☐ This action	·								
	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims									
İ		15 is/are pending in the application.								
	•	4a) Of the above claim(s) is/are withdrawn from consideration.								
		5) Claim(s) is/are allowed.								
		is/are rejected.								
		is/are objected to.			•					
	8)⊠ Claim(s) <u>1-1</u> Application Papers	1 <u>5</u> are subject to restriction and/or el	ection requiren	nent.						
-	9)☐ The specifica	ation is objected to by the Examiner.								
		(s) filed on is/are: a)□ accept		ted to by the Exam	niner.					
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).									
Ì		d drawing correction filed on			• • •	r. ·				
		corrected drawings are required in reply			•					
1	12)☐ The oath or declaration is objected to by the Examiner.									
	Priority under 35 U.S.C. §§ 119 and 120									
	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).									
	a) ☐ All b) ☐ Some * c) ☐ None of:									
1	1. Certified copies of the priority documents have been received.									
	2. Certified copies of the priority documents have been received in Application No									
	Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.									
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional approvisional approvision										
	a) \square The translation of the foreign language provisional application has been received.									
	15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s)									
1	1) Notice of References	Cited (PTO-892)	□	Interview Summer "	3TO 442) Dam (N 1					
	Notice of Draftspersor Information Disclosure	olted (PTO-892) n's Patent Drawing Review (PTO-948) e Statement(s) (PTO-1449) Paper No(s)	4) <u> </u> 5) <u> </u> 6) <u> </u>		PTO-413) Paper No(s) tent Application (PTO-					
	S. Patent and Trademark Office TO-326 (Rev. 04-01)	Office Action	on Summary		Part of Paper No. 5					

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CLAIMS 1-15 ARE PRESENTED FOR EXAMINATION

Detailed Action

Applicant is advised that pursuant to 37 CFR 1.126 the numbers of claims 11-16 have been changed to 10-15 since claim 10 was missing from the application as filed.

Accordingly, applicant is advised to renumber the claims in their file.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 10 and 11, drawn to compositions of prolonged release formulations.
- II. Claims 9 and 12-15.drawn to processes for the preparation of sustained/prolonged release formulations.

Inventions of Group I and II are related as process and apparatus (compositions) for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process of Group II, the preparation of sustained/prolonged release formulations, can be carried out by various procedures to prepare sustained release formulations that are available commercially.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Further restriction may be required.

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No telephone communication was made on this restriction requirement because the

restriction is complex. (MPEP 812.01).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Theodore J. Criares whose telephone number is 308-

4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday

through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Theodore J. Criares can be reached on 305-1877. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-746-6897

for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is 308-1235.

neodore J. Criares

Primary Examiner

Art Unit 1617

tjc

June 25, 2003